

February 25, 2002 Meeting Summary - DRAFT

Purpose

This document summarizes the February 25, 2002 GTF meeting. It presents some of the broader questions addressed at the meeting and proposes some answers to those questions.

Meeting Overview

The Genetics Task Force (GTF) heard presentations on: 1) Washington state laws that regulate the use of genetic information in health, disability, life and property and casualty insurance; 2) How insurance companies use genetic information; 3) Why genetic discrimination and genetic privacy are important issues; 4) The history of eugenics and genetic discrimination in the U.S.; 5) Genetic privacy and anti-discrimination legislation in other states; 6) Evidence of genetic discrimination in Washington State; and 7) Oregon's Genetic Privacy Law. Information presented at the meeting addressed several questions facing the task force and introduced new ideas and questions to be answered over the course of the Genetics Task Force's tenure.

Questions Answered

Presentations and discussions at the second GTF meeting addressed the following questions:

1. *Do existing state laws address the use of preexisting conditions for insurance coverage? If so, what do the laws say about genetic testing and genetic discrimination and who do/don't they apply to?*

Existing state laws regulate the use of preexisting conditions for some types of insurance. The definition of 'preexisting condition' varies by type of insurance while some types of insurance do not define 'preexisting condition'. RCW 48.84.020 (LTC) and RCW 48.43.005 (health plan) are examples of different definitions for different types of insurance. The specified time period applicable to a preexisting condition varies among different types of insurance. Health plans (defined in RCW 48.43.005(19)) offered by health carriers are prohibited from treating genetic information as a health condition in the absence of a diagnosis of the condition related to such information (WAC 284.43.720), i.e. genetic information cannot be used to define a preexisting condition unless it is accompanied by a diagnosis of that condition.

RCW 48.43.005(19): Health plans include any policy, contract, or agreement offered by a health carrier to provide, arrange, reimburse, or pay for health care services except the following (these are disability income type insurance coverage and some are not regulated by the Office the Insurance Commissioner): (a) Long-term care insurance governed by chapter 48.84 RCW; (b) Medicare supplemental health insurance governed by chapter 48.66 RCW; (c) Limited health care services offered by limited health care service contractors in accordance with RCW 48.44.035; (d) Disability income; (e) Coverage incidental to a property/casualty liability insurance policy such as automobile personal injury protection coverage and homeowner guest medical; (f) Workers' compensation coverage; (g) Accident only coverage; (h) Specified disease and hospital confinement indemnity when marketed solely as a supplement to a health plan; (i) Employer-sponsored self-funded health plans; (j) Dental only and vision only coverage; and (k) Plans deemed by the insurance commissioner to have a short-term limited purpose or duration, or to be a student-only plan that is guaranteed renewable while the covered person is enrolled as a regular full-time undergraduate or graduate student at an accredited higher education institution,

after a written request for such classification by the carrier and subsequent written approval by the insurance commissioner.

Individual, small and large group health insurance plans may contain a waiting period of up to 9 months for coverage of preexisting conditions. (RCW 48.43.012; RCW 48.43.025 (1); RCW 48.43.025 (2)). But genetic information may not be considered a preexisting condition unless it is accompanied by a diagnosis of the condition, e.g. a person who carries the Huntington disease (HD) mutation but does not have associated symptoms, is not receiving treatment, and does not have a diagnosis of HD may not be excluded from coverage for HD associated health care during the preexisting condition waiting period. However, if the person has the mutation, has symptoms, has been diagnosed, and is receiving treatment prior to the effective date of coverage, the carrier can exclude coverage related to the condition during the preexisting condition waiting period.

Individual disability insurance can be underwritten based on health care information and can exclude preexisting conditions. Group disability insurance plans can be underwritten based on health care information and may or may not be guaranteed renewable or noncancellable. Depending on the plan, using genetic information to define a preexisting condition may not be prohibited by law under these types of insurance. Health plans offered by disability carriers follow the same rules as health plans offered by health carriers.

Long-term care insurance cannot exclude or limit coverage for preexisting conditions that received medical attention more than one year prior to coverage or more than six months after the effective date of coverage. (RCW 48.84.040). Depending on the plan, using genetic information to define a preexisting condition may not be prohibited by law under these types of insurance.

Medicare supplemental insurance cannot exclude or limit benefits for losses incurred more than three months from the effective date of coverage because it involved a preexisting condition. Depending on the plan, using genetic information to define a preexisting condition may not be prohibited by law under these types of insurance.

In general, life insurance can use health care information to deny coverage or to set initial rates; i.e. there are no laws preventing the use of preexisting conditions in life insurance underwriting, the insurer can underwrite for any reason. A policy cannot be cancelled after issuance based on emerging health issues. Rates are term-based and may be periodically re-classified.

Property and casualty insurance plans generally do not consider health care information, however it is not specifically prohibited. An insurer using health care information to deny, cancel or set rates must justify the action.

2. How do health insurers use genetic information?

Standard practice for a health carrier such as Regence Blue Shield with respect to genetic information is to treat it like other health-related information. For example, test results may be requested to verify claims for payment of a genetic test. In this case, the test results per se are not evaluated; rather the test results are used to prove that the charges for the test are legitimate.

Regence does not (and cannot by law) use genetic information to deny, delay or set rates for health insurance policies.

In general, according to the OIC, genetic information cannot be used to deny, cancel or non-renew a policy or to rate a consumer for health insurance. However, ESSB 6067 allows a health carrier to require individual health insurance applicants to complete a questionnaire designed to screen out the 8% of enrollees who are the costliest to treat. The questionnaire identifies conditions currently or previously under treatment; it does not ask specifically about genetic information or family history.

3. What are some of the legislative approaches taken by other states to protect genetic privacy and prevent discrimination?

Forty-six states enacted targeted genetics legislation prior to 2001. The adopted statutes reflect widely divergent approaches to regulating genetic information. The scope of the legislation and definitions within the legislation vary between states. Some states use a narrow definition of genetic information. For example, a number of state statutes limit discrimination based only on “the results of a genetic test” defined as examination of an individual’s genes or gene products. Other states have broadly defined genetic information, so that the term also includes information from family medical histories, genetic test results of family members, and inherited characteristics. Still another group of states have tried to limit these broad definitions by excluding results of routine physical or chemical tests, indirect manifestations of genetic disorders, and/or accepted scientific practices.

Existing state genetic information privacy and nondiscrimination laws also differ in the protections they afford and in their enforcement schemes. Access, storage, and distribution of genetic information may be regulated. Additionally, some states provide for specific private or public enforcement of the anti-discrimination or privacy measures.

Tables and summaries provided at the February 25th meeting describe the different policy approaches taken by other states.

4. How have research efforts in Oregon been affected by genetics privacy and anti-discrimination legislation?

Initial genetics privacy legislation in Oregon (OR SB 276) failed to draw a distinct line between clinical and research uses of DNA and genetic information. Many researchers perceived the first law as too restrictive and claimed that it prevented them from conducting research that could lead to important medical discoveries. This led to a lengthy review and revision process resulting in new legislation (OR SB 114) that provided more detail on the use of genetic information in research. The new law specifically defines the circumstances under which a DNA sample or genetic information may be used in research. Specifically the law requires that all genetic research undergo IRB review and comply with the minimum standards of 45 CFR 46, it also requires specific consent for participation in genetic research. The presentation given on February 25th describes additional requirements laid out in the law.

5. What evidence exists regarding genetic discrimination and/or privacy violations in Washington State?

A representative from the Washington State Human Rights Commission (WSHRC) reported that no complaints regarding genetic discrimination have been filed with WSHRC. She also reported that a review of WSHRC rules indicated that they are broad enough to allow the agency to investigate and take action against such claims if they arise.

A representative from the Washington State Department of Health Genetic Services Office reported that among the complaints received by that office, only one falls into the category of genetic discrimination. This involved a woman who was denied car insurance based on a family history of seizures despite the fact that she did not have a personal history of seizures.

No other reports or testimonies were given at the February 25th meeting regarding evidence of genetic discrimination in Washington.

Other Questions Arising at the February 25th Meeting

1. What states, if any, carved out exceptions for research in their genetic privacy legislation?

The following is a sample of exceptions for research purposes adopted by some states as part of their genetic privacy laws. Some states limited the scope of their laws to apply only to insurance or employment and, in most cases, these narrower laws do not address the issue of research. Text from each statute was obtained from links to the statutes provided on the NCSL website (<http://www.ncsl.org/programs/health/genetics/prt.htm>).

Arkansas – SB 764 permits use of biological samples for genetic studies without patient consent if identifiers such as name and social security number are removed. SB 7764 protects genetic information obtained in research from subpoenas and disclosure to employers or insurance companies

Colorado – 10-3-1104.7 states “(3) (a) Information derived from genetic testing shall be confidential and privileged. Any release, for purposes other than diagnosis, treatment, or therapy, of genetic testing information that identifies the person tested with the test results released requires specific written consent by the person tested. (b) Any entity that receives information derived from genetic testing may not seek, use, or keep the information for any nontherapeutic purpose or for any underwriting purpose connected with the provision of health care insurance, group disability insurance, or long-term care insurance coverage... (5) Notwithstanding the provisions of subsection (3) of this section, any research facility may use the information derived from genetic testing for scientific research purposes so long as the identity of any individual to whom the information pertains is not disclosed to any third party; except that the individual's identity may be disclosed to the individual's physician if the individual consents to such disclosure in writing.”

Georgia - 33-54-6 is similar to Colorado's law, it also states “Notwithstanding the provisions of Code Sections 33-54-3 and 33-54-4, any research facility may conduct genetic testing and may use the information derived from genetic testing for scientific research purposes so long as the identity of any individual tested is not disclosed to any third party, except that the individual's identity may be disclosed to the individual's physician with the consent of the individual.

Louisiana – 22:213.7 states “A general authorization for the release of medical records or medical information shall not be construed as an authorization for disclosure of genetic information. With respect to medical records that contain genetic information, the requirements for disclosure of genetic information under this Section must be complied with. D. The requirements of this Section shall not apply to the genetic information obtained:

(1) ... (4) *For anonymous research where the identity of the subject will not be released.* ... (7).

Massachusetts - Chapter 254 of the Acts of 2000 states “b) Hospital, dispensary, laboratory, hospital-affiliated registry, physician, insurance institution, insurance support organization, or insurance representative, and commercial genetic testing company, agency, or association reports and records pertaining to any genetic information shall not be public records, and the contents thereof shall not be divulged by any person having charge of or access to the same without informed written consent, except upon proper judicial order or to a person whose official duties, in the opinion of the commissioner, entitle receipt of the information contained therein, or except in connection with life, disability, and long term care insurance as authorized pursuant to chapter 175I or as confidential research information for use in epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease. A laboratory receiving a request to conduct a genetic test from a facility, as defined in section 70E, or a physician or health care provider may conduct the requested test only when the request is accompanied by a signed statement of the medical practitioner ordering the test warranting that the appropriate prior written consent has been obtained from the patient except where the test is conducted as confidential research information for use in epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease. The signed request authorizes the laboratory to perform the test and disclose the results to the medical practitioner.”

Missouri - 375.1309 states “1. Any person who, in the ordinary course of business, practice of a profession or rendering of a service, creates, stores, receives or furnishes genetic information, as such term is defined in subdivision (3) of section 375.1300, shall hold such information as confidential medical records and shall not disclose such genetic information except pursuant to written authorization of the person to whom such information pertains or to that person's authorized representative. The requirements of this section shall not apply to: (1) Statistical data compiled without reference to the identity of an individual; (2) Health research conducted in accordance with the provisions of the federal common rule protecting the rights and welfare of research participants (45 CFR 46 and 21 CFR 50 and 56), or to health research using medical archives or databases in which the identity of individuals is protected from disclosure by coding or encryption, or by removing all identities; (3) The release of such information pursuant to legal or regulatory process; or (4) The release of such information for body identification.”

Nebraska - The definition of genetic test states that “Genetic test does not include a procedure performed as a component of biomedical research that is conducted pursuant to federal common rule under 21 C.F.R. parts 50 and 56 and 45 C.F.R. part 46, as such regulations existed on the effective date of this act”

Nevada - NRS 629.151 “Obtaining genetic information of person without consent unlawful; exceptions. It is unlawful to obtain any genetic information of a person without first obtaining the informed consent of the person or the person’s legal guardian pursuant to NRS 629.181, unless the information is obtained: 1... 4. For use in a study where the identities of the persons from whom the genetic information is obtained are not disclosed to the person conducting the study; ...6.

New Jersey – 10:5-45 “No person shall obtain genetic information from an individual, or from an individual's DNA sample, without first obtaining informed consent from the individual or the individual's representative according to regulations promulgated by the Commissioner of Health and Senior Services, in consultation with the Commissioner of Banking and Insurance, pursuant to subsection b. of section 9 of P.L.1996, c.126 (C.10:5-48). a. The requirements of this section shall not apply to genetic information obtained: (1) ... (5) For anonymous research where the identity of the subject will not be released... (7).”

Texas - Art. 9031. Prohibited Use of Genetic Information makes an exception for the disclosure of genetic information if the disclosure is “(1) for information from a research study in which the procedure for obtaining informed written consent and use of the information is governed by national standards for protecting participants involved in research projects, including guidelines issued under 21 C.F.R. Part 50 and 45 C.F.R. Part 46; (2) the information does not identify a particular individual; and (3) the information is provided to the Texas Department of Health to comply with Chapter 87, Health and Safety Code.

On the federal level, HIPAA privacy rules contain exceptions for research. Please see <http://www.hhs.gov/ocr/hipaa/research.html>.

“To use or disclose personal health information (PHI) without authorization by the research participant, a covered entity must obtain one of the following:

- Documentation that an alteration or waiver of research participants' authorization for use/disclosure of information about them for research purposes has been approved by an Institutional Review Board (IRB) or a Privacy Board. This provision of the Privacy Rule might be used, for example, to conduct records research, when researchers are unable to use de-identified information and it is not practicable to obtain research participants' authorization.
- Representations from the researcher, either in writing or orally, that the use or disclosure of the PHI is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any PHI from the covered entity, and representation that PHI for which access is sought is necessary for the research purpose. This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study.
- Representations from the researcher, either in writing or orally, that the use or disclosure being sought is solely for research on the PHI of decedents, that the PHI being sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is being sought.

A covered entity may use or disclose PHI for research purposes pursuant to a waiver of authorization by an IRB or Privacy Board provided it has obtained documentation of *all* of the following:

- A statement that the alteration or waiver of authorization was approved by an IRB or Privacy Board that was composed as stipulated by the Privacy Rule;
- A statement identifying the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;
- A statement that the IRB or Privacy Board has determined that the alteration or waiver of authorization, in whole or in part, satisfies the following eight criteria:
 - The use or disclosure of PHI involves no more than minimal risk to the individuals;
 - The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;
 - The research could not practicably be conducted without the alteration or waiver;
 - The research could not practicably be conducted without access to and use of the PHI;
 - The privacy risks to individuals whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;
 - There is an adequate plan to protect the identifiers from improper use and disclosure;
 - There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this subpart.
- A brief description of the PHI for which use or access has been determined to be necessary by the IRB or Privacy Board;
- A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures as stipulated by the Privacy Rule; and
- The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

2. *How have other states addressed the issue of genetic information in the context of adoption? Do existing Washington state laws address this issue?*

Information about how other states have addressed the issue genetic information in adoption is forthcoming.

Washington state law RCW 26.33.350 pertains to the disclosure of medical information to the adoptive parents. It states “(1) Every person, firm, society, association, corporation, or state agency receiving, securing a home for, or otherwise caring for a minor child shall transmit to the prospective adopting parent prior to placement and shall make available to all persons with whom a child has been placed by adoption a complete medical report containing all known and available information concerning the mental, physical, and sensory handicaps of the child.

(2) The report shall not reveal the identity of the birth parent of the child except as authorized under this chapter but shall include any known or available mental or physical health history of the birth parent that needs to be known by the adoptive parent to facilitate proper health care for the child or that will assist the adoptive parent in maximizing the developmental potential of the child.

(3) Where known or available, the information provided shall include:

(a) A review of the birth family's and the child's previous medical history, including the child's x-rays, examinations, hospitalizations, and immunizations. After July 1, 1992, medical histories shall be given on a standardized reporting form developed by the department;

(b) A physical exam of the child by a licensed physician with appropriate laboratory tests and X-rays;

(c) A referral to a specialist if indicated; and

(d) A written copy of the evaluation with recommendations to the adoptive family receiving the report.

(4) Entities and persons obligated to provide information under this section shall make reasonable efforts to locate records and information concerning the child's mental, physical, and sensory handicaps. The entities or persons providing the information have no duty, beyond providing the information, to explain or interpret the records or information regarding the child's present or future health.”

RCW 26.33.380 pertains to disclosure of family background and social history. It states “(1) Every person, firm, society, association, corporation, or state agency receiving, securing a home for, or otherwise caring for a minor child shall transmit to the prospective adopting parent prior to placement and shall make available to all persons with whom a child has been placed by adoption, a family background and child and family social history report, which includes a chronological history of the circumstances surrounding the adoptive placement and any available psychiatric reports, psychological reports, court reports pertaining to dependency or custody, or school reports. Such reports or information shall not reveal the identity of the birth parents of the child but shall contain reasonably available nonidentifying information.

(2) Entities and persons obligated to provide information under this section shall make reasonable efforts to locate records and information concerning the child's family background and social history. The entities or persons providing the information have no duty, beyond providing the information, to explain or interpret the records or information regarding the child's mental or physical health.

3. Do existing laws have provisions that regulate the genetic testing of minors?

At least one state has a provision in its genetic privacy law with respect to genetic testing and minors under age 18. Illinois law 410.513 states “Sec. 30. Disclosure of person tested and test results. (a) No person may disclose or be compelled to disclose the identity of any person upon whom a genetic test is performed or the results of a genetic test in a manner that permits

identification of the subject of the test, except to the following persons: ... (6) In the case of a minor under 18 years of age, the health care provider who ordered the test shall make a reasonable effort to notify the minor's parent or legal guardian if, in the professional judgment of the health care provider, notification would be in the best interest of the minor and the health care provider has first sought unsuccessfully to persuade the minor to notify the parent or legal guardian or after a reasonable time after the minor has agreed to notify the parent or legal guardian, the health care provider has reason to believe that the minor has not made the notification. This paragraph shall not create a duty or obligation under which a health care provider must notify the minor's parent or legal guardian of the test results, nor shall a duty or obligation be implied. No civil liability or criminal sanction under this Act shall be imposed for any notification or non-notification of a minor's test result by a health care provider acting in good faith under this paragraph. For the purpose of any proceeding, civil or criminal, the good faith of any health care provider acting under this paragraph shall be presumed.”

At least two professional society statements have been issued regarding genetic testing in children. The American Society of Human Geneticists (ASHG)/American College of Medical Geneticists (ACMG) report (1995) and the National Society of Genetic Counselors (NSGC) report (1995) both outline the appropriate circumstances under which a child should undergo a genetic test and recommend specific roles for health care providers in the testing process. However neither report discusses the privacy of the minor’s genetic information. The ASHG/ACMG report briefly reviews the conflicting legal aspects of parental authority and the degree of autonomy granted to minors. Both reports consider the ethical issues of beneficence/nonmaleficence and autonomy in the context of genetic testing in children.

4. What is the Medical Information Bureau?

The Medical Information Bureau (MIB) is a non-profit association of U.S. and Canadian insurance companies. Member agencies send specific health-related information about individuals who apply to the agencies for individual life, health, disability or long-term care insurance to MIB. MIB stores the information and provides it upon request as a service to its other members. MIB’s mission is to detect and deter attempts by applicants of life, health, disability, or long-term insurance who would omit or misrepresent facts. Please see the MIB website for more information. <http://www.mib.com/html/home.html>

5. What state and federal laws define the types of genetic information employers can request and how they can use the information?

No current federal or state law specifically regulates the types of genetic information an employer can request. However, some federal and state laws may apply to the issue. See the paper titled “Genetics, Health Care and the Law” by Colleen Kinerk in the April 12th meeting binder. Another resource of interest is an article by Paul Stephen Miller, “Genetic Discrimination in the Workplace” 26 J. of Law, Medicine & Ethics 189 (1998).

On the federal level, the American’s with Disabilities Act regulates the circumstances under which an employer can subject potential and current employees to medical testing. The ADA states that before making an offer of employment, an employer may not ask job applicants about the existence, nature, or severity of a disability. Applicants may be asked about their ability to perform job functions. A job offer may be conditioned on the results of a medical examination,

but only if the examination is required for all entering employees in the same job category. Medical examinations of existing employees must be job-related and consistent with business necessity. The Equal Employment Opportunities Commission (EEOC) writes rules pertaining to and oversees the implementation of the ADA. The EEOC rules address the retention, storage and use of employee's health information. The EEOC interprets the scope of the ADA to include genetic tests and genetic information. The EEOC considers that employers who discriminate against employees on the basis of predictive genetic tests "regard" the employees as having a disabling impairment and are therefore acting in violation of the ADA (2EEOC Compliance Manual, secs. 902-45, March 14, 1995).

6. What existing state/federal laws provide protection against genetic discrimination in employment?

The Washington Law Against Discrimination (WLAD) (RCW 49.60) prohibits employers from refusing to hire, discharging or barring, or discriminating against any person in compensation based on any sensory, mental, or physical handicap. The American's with Disabilities Act (ADA) extends this protection to persons regarded as having a disabling impairment. The EEOC's interpretation of the ADA to include predictive genetic tests has not been tested in court.

Questions Remaining

1. How should legislation in WA define DNA, genetic information, etc...? (ongoing discussion)

Note: ESSB 5207 changed the definition of 'health care information' to include "an individual's deoxyribonucleic acid and identified sequence of chemical base pairs." The bill was delivered to the Governor on March 14th, 2002.

- 2. What are the concerns of academic and private researchers with respect to access to and use of DNA? (April 12, 2002 meeting)*
- 3. What are the future directions and development plans for the biotech industry in WA? (April 12, 2002 meeting)*
- 4. What are appropriate and reasonable incentives to stimulate genetic research and development? (April 12, 2002 meeting)*